REMARKS

Applicants and their representative respectfully acknowledge the time and courtesy extended by the Examiners in conducting the Interview of November 5, 2002. The above amendments and the remarks below were discussed at the Interview.

The claims have been amended to remove the "sprayed from a solution onto particles of an inert carrier" language in order to focus on the issue of drospirenone in micronized form. The claims are also amended to recite that the compositions or kit components are orally administrable. These amendments were not made for patentability purposes but for practicality purposes since the prior prosecution all focused on compositions of micronized drospirenone useful as oral contraceptives. The further amendments to the claims are linguistic in nature and do not narrow the scope of the claims. No amendment should be interpreted as an acquiescence to any objection or rejection in this application. Applicants intend to file one or more continuing and/or divisional applications directed to any subject matter which has been canceled by the above amendments.

The only grounds of rejection made in the Final Office Action were a rejection of claims 1, 3-7, 9-14, 16-17 and 36-40 under 35 U.S.C. § 103 for allegedly being obvious over Gast (WO 98/04269) and a rejection of claims 18-22 under 35 U.S.C. § 103 for allegedly being obvious over Gast (WO 98/04267). These rejections are respectfully traversed and, since the base issues are so interrelated, the rejections will be discussed together.

As acknowledged in the previous Office Actions, Gast fails to teach a composition containing drospirenone in micronized form. As a basis for the rejection, it is apparently alleged that micronization, or any other dosage form or regimen, of any known pharmaceutically active agent would have been obvious to one of ordinary skill in the art. It is further alleged in the Final Office Action that "micronizing the particles of the active

agents increases their surface area, thereby resulting in more dissemination .. which would result in increased bioavailability of the actives *in vivo*."

Initially, applicants respectfully submit that the mere knowledge in the art that drospirenone is a pharmaceutically active agent does not provide the requisite motivation to one of ordinary skill in the art to support obviousness (under 35 U.S.C. § 103) of an orally administrable composition comprising drospirenone in micronized form. Surely, it was known in the art that some pharmaceuticals have advantages in administration when provided in micronized form. See, e.g., the de Lignieres article cited in the concurrently filed Information Disclosure Statement. But it was also known in the art that the effectiveness of some pharmaceuticals is unaffected or hindered by providing them in micronized form.

In order to suggest applicants' invention, Gast must be modified, at least, by providing the drospirenone in micronized form. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 23 USPQ 2d 1780 (Fed. Cir. 1992). Nothing suggests such desirability.

Even if there were a hint of such desirability, it has been held that the desirability must be of such degree that there would have been a "reasonable expectation of success," established by the prior art, for such modified method. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); and In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988). Such an expectation also has not been established on the record.

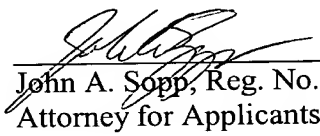
Further supplemental evidence on these points will be included in a Declaration under 37 C.F.R. § 1.132, which is being prepared and will be submitted shortly.

For all of the above reasons, the rejections under 35 U.S.C. § 103 should be withdrawn.

Favorable action on the application is earnestly solicited. The Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Amend claims 1, 3, 5-7, 9, 10, 17, 18 and 36 to read as follows (a marked-up version showing the changes is provided in the attached Appendix):

1. (Twice Amended) A pharmaceutical composition comprising~~, as a first active agent, 6β,7β;15β,16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone, drospirenone, in an amount corresponding to a daily dosage, on administration of the composition, of~~ from about 2 mg to about 4 mg of micronized drospirenone, ~~and, as a second active agent, 17α-ethinylestradiol in an amount corresponding to a daily dosage of from~~ about 0.01 mg to about 0.05 mg of 17α-ethinylestradiol, ~~together with~~ and one or more pharmaceutically acceptable carriers, the composition being in an orally administrable form ~~or excipients, said drospirenone being in micronized form or sprayed from a solution onto particles of an inert carrier~~.

3. (Twice Amended) A composition according to claim 1, ~~comprising~~ wherein the amount of drospirenone ~~in an amount corresponding to a daily dosage of~~ is from about 2.5 mg to about 3.5 mg.

5. (Twice Amended) A composition according to claim 1, ~~comprising~~ wherein the amount of ethinylestradiol ~~in an amount corresponding to a daily dosage of~~ is from about 0.015 mg to about 0.04 mg.

6. (Twice Amended) A composition according to claim 1, ~~comprising an~~ wherein the amount of drospirenone ~~corresponding to a daily dosage of~~ is from about 3.0 to about 3.5 mg and the amount of ethinylestradiol ~~in an amount corresponding to~~ is from about 0.015 to about 0.03 mg.

7. (Amended) A composition according to claim 1 wherein the pharmaceutically acceptable carrier ~~or excipient is selected so as to promote~~ promotes rapid dissolution of the ~~first and second active agents~~ drospirenone and 17α-ethinylestradiol, the dissolution being determined by applying the USP paddle method, the dissolution media being water at 37°C and the stirring rate being 50 rpm, and wherein rapid dissolution means that at least 70% of each of drospirenone and 17α-ethinylestradiol ~~the first and second active substances~~ are dissolved within 30 minutes.

9. (Twice Amended) A composition according to claim 7, wherein at least 80% of each of drospirenone and 17α-ethinylestradiol ~~the first and second active agents~~ are dissolved within 20 minutes.

10. (Twice Amended) A pharmaceutical kit ~~consisting of~~ comprising a number of separately packaged, ~~and~~ individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of ~~6β,7β;15β,16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone,~~ micronized drospirenone~~,~~ in an amount of from about 2 mg to about 4 mg and 17α-ethinylestradiol in an

amount from about 0.01 to about 0.05 mg~~, said drospirenone and said 17α-ethinylestradiol being in micronized form or sprayed from a solution onto particles of an inert carrier~~.

17. (Twice Amended) A kit according to claim 10, wherein the ~~at least 21~~ daily dosage units comprise drospirenone in an amount of from about 3.0 to about 3.5 mg and 17α-ethinylestradiol in an amount ~~corresponding to~~ of from about 0.015 to about 0.03 mg.

18. (Twice Amended) A pharmaceutical kit ~~consisting of~~ comprising a number of separately packaged, ~~and~~ individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days, wherein at least 21 of said daily dosage units comprise a combination of ~~6β,7β;15β,16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone,~~ micronized drospirenone~~,~~ in an amount of from about 2 mg to about 4 mg and 17α-ethinylestradiol in an amount from about 0.01 to about 0.05 mg, wherein ~~said drospirenone and said 17α-ethinylestradiol are in micronized form or sprayed from a solution onto particles of an inert carrier, and wherein~~ at least 1 but no more than 7 of said daily dosage units contain 17α-ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.

36. (Twice Amended) The composition of claim 1, wherein the drospirenone is in the form of ~~an ester or~~ a prodrug of the compound.

Claims 41-43 have been added.